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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,575	04/05/2001	Charles E. Loomis	HO-P02054US1	3001
26271	7590	08/16/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			CYGAN, MICHAEL T	
			ART UNIT	PAPER NUMBER
			2855	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/826,575	Applicant(s) LOOMIS ET AL.	
	Examiner Michael Cygan	Art Unit 2855	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-16, 22-26, 32-35 and 57-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-16, 22-26, 32-35, 57-66, 68, 69 and 71 is/are rejected.
- 7) ☒ Claim(s) 67, 70 and 72 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 July 2004 has been entered.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the breakable glass enclosure of claims 63 and 69 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Amendment to the specification referring to the new drawing will be required.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the

appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites a glass enclosure formed as a layer of a container portion which is integrally formed as one piece with the pump portion. However, while the

specification discloses a glass enclosure within an integrally formed pump-container shell, the specification does not describe the glass enclosure as being integrally formed with the polymeric pump-container portion. This rejection could be overcome by describing the glass enclosure as an enclosure resting within the container portion, instead of referring to the glass as a second layer which is included in the container portion.

4. Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose the step of breaking the glass before operating the squeeze bulb as is claimed. This rejection could be overcome by deleting the "wherein..." clause from claim 69.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5, 8-14, 16, 22-26, 32-35, 57, 62, 64-66, 68, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) and in view of U. S. Patent Number 3,840,009 (Michaels). OSHA discloses a sealed testing apparatus comprising a bulb (i.e., a pump) and a container portion (smoke tubes) having frangible ends, an outlet, and containing a chemical substance such as stannic chloride ( $\text{SnCl}_4$ ) producing an "irritant smoke" upon exposure to air. The apparatus produces smoke used to check for leaks in equipment such as face seals, the smoke carrying an irritating scent noticeable by the equipment wearer. OSHA further discloses providing such an apparatus, storing a chemical having a selected scent in the apparatus prior to use, breaking an end portion, causing a chemical reaction between the chemical and air (the local environment), and operating a bulb to start a smoke test, and directing the smoke outward of the container and towards equipment such as a face seal. The smoke is visually observed as the test operator visually directs the smoke in three circumferential passes at a specified distance from the face seal. See page 227.

OSHA does not teach an integral tube-pump design and the method of forming that design. Garren '241 teaches that it is known to assemble and use plastic tube-pump integral (one piece) pipettes wherein the pump is seamlessly joined to the tube (Figures 1-3) in place of glass/rubber bulb pipettes (columns 1-2) to form a substantially permanent structure. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to form an integral plastic pipette and use an integral plastic pipette as taught by Garren '241 in place of the two piece pipette disclosed by OSHA, since this would allow operation of the protocol without danger of untimely glass breakage, reduced cost, and reduced assembly time (Garren column 1, line 48 through column 2, line 17). Since the pipette of Garren is formed by the thermal expansion of a seamless tube, the pipette is also seamless.

OSHA does not teach the composition of the device having substantial impermeability and being a laminate of two distinct material layers, one of which being a flexible (low-density) polyethylene, the other comprising a material which may be mylar (an inert, low-permeability material which is inherently substantially more impermeable than the polyethylene). Michael teaches a vapor delivery device in which the plastic pump and tube are formed of polyethylene laminates, one of which may be a polyethylene-Mylar laminate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyethylene laminates including a polyethylene-Mylar laminate as taught by Michael in the invention taught by OSHA to form the casing material, since this will achieve both flexibility and substantial impermeability (see Michaels column 7, lines 49-52 and column 8, lines 1-7) of the device.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) and in view of U. S. Patent Number 3,840,009 (Michaels) as applied to claim 1, further in view of U. S. Patent Number 5,073,347 (Garren '347). OSHA teaches the claimed invention except for the plastic being low-density polyethylene, or may be two different materials for bulb and tube. Garren '347 teaches the composition of a plastic pipette being low-density polyethylene or two different materials for bulb and tube (column 9, lines 41-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use low-density polyethylene or two different materials for bulb and tube as taught by Garren '347 in the invention taught by OSHA, since Garren teaches that such materials are inexpensive and resistant to contamination and breakage during transportation (column 1, lines 38-51).
7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over OSHA in view of U.S. 3,834,241 (Garren '241) and in view of U. S. Patent Number 3,840,009 (Michaels) as applied to claim 1, further in view of Rodrigues (US 3,938,392). OSHA in view of Garren '241 discloses a testing apparatus comprising a bulb (i.e., a pump) and a container portion (smoke tubes) having frangible ends and containing a chemical substance producing an "irritant smoke" upon exposure to air. The apparatus produces smoke



used to check for leaks in equipment such as face seals. See page 227.

OSHA teaches the claimed invention except for an integral tube-pump design having a finger hole in the pump area. Rodrigues teaches the provision of a finger hole in a flexible plastic pipette bulb (Figure 1) which is used as an improvement over the known glass/rubber two piece bulb (column 1, lines 5-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a finger hole as taught by Rodrigues in the invention taught by OSHA in view of Gerren, since this would allow operation of the protocol without danger of untimely glass breakage (see Rodrigues column 1, lines 11-12) or human injury (see OSHA page 277 lines 6-10) caused by operation of a two piece system having a glass component.

8. Claims 58, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) and in view of U. S. Patent Number 5,302,344 (Perlman). OSHA discloses a sealed testing apparatus comprising a bulb (i.e., a pump) and a container portion (smoke tubes) having frangible ends, an outlet, and containing a chemical substance such as stannic chloride ( $\text{SnCl}_4$ ) producing an "irritant smoke" upon exposure to air. The apparatus produces smoke used to check for leaks in equipment such as face seals, the smoke carrying an irritating scent noticeable by the equipment wearer. OSHA

further discloses providing such an apparatus, storing a chemical having a selected scent in the apparatus prior to use, breaking an end portion, causing a chemical reaction between the chemical and air (the local environment), and operating a bulb to start a smoke test, and directing the smoke outward of the container and towards equipment such as a face seal. The smoke is visually observed as the test operator visually directs the smoke in three circumferential passes at a specified distance from the face seal. See page 227.

OSHA does not teach an integral tube-pump design and the method of forming that design. Garren '241 teaches that it is known to assemble and use plastic tube-pump integral (one piece) pipettes wherein the pump is seamlessly joined to the tube (Figures 1-3) in place of glass/rubber bulb pipettes (columns 1-2) to form a substantially permanent structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form an integral plastic pipette and use an integral plastic pipette as taught by Garren '241 in place of the two piece pipette disclosed by OSHA, since this would allow operation of the protocol without danger of untimely glass breakage, reduced cost, and reduced assembly time (Garren column 1, line 48 through column 2, line 17).

OSHA does not teach the packaging of a pipette in a laminate bag. Perlman discloses laminate metal foil packaging film (inherently substantially more fluid impermeable than a polymer such as polyethylene) for wrapping

pipettes; see column 8, lines 1-39. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a laminate packaging film as taught by Perlman in the invention taught by OSHA to package the pipette, since Perlman teaches that the laminates provide a sterile storage which prevents contamination prior to use. The recitation of the use of the apparatus is not given patentable weight, since the claims are directed towards the method of forming an apparatus; since the method of forming the apparatus having the claimed structure is made obvious over the applied references, the claims are properly rejected.

9. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) and in view of U. S. Patent Number 5,302,344 (Perlman) as applied to claims 36 and 58, further in view of U. S. Patent Number 6,098,802 (Asa). OSHA in view of Garren and Perlman teaches the claimed invention except for the packaging of a pipette in a mylar bag. Asa teaches that mylar is an equivalent packaging material to metal foil for the purpose of maintaining sterile pipettes; see column 5, line 64 through column 6, line 8. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use mylar as the packaging material in the invention taught by OSHA in view of Garren and Perlman to form an inert packaging, since Asa teaches that mylar is an equivalent packaging material

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to metal foil (as taught by Perlman) for the purpose of maintaining sterile pipettes.

***Allowable Subject Matter***

10. Claims 67, 70, and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. The following is a statement of reasons for the indication of allowable subject matter: The prior art neither discloses nor fairly teaches a method of fit testing respiratory equipment having either a fluid impermeable bag in combination with the other positively recited limitations of claim 70 or a maximum pumping capacity of an integrally formed bulb/container apparatus in combination with the other positively recited limitations of claim 22; or a method of manufacturing an apparatus having the recited limitations of claim 32 comprising the step of selecting a squeeze bulb portion having a pumping capacity below a predetermined capacity.

***Response to Arguments***

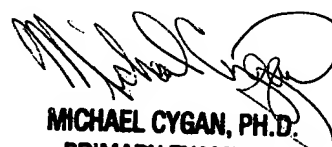
12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Cygan whose telephone number is (571) 272-2175. The examiner can normally be reached on 8:30-6 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Lefkowitz can be reached on 571-272-2180. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**MICHAEL CYGAN, PH.D.**  
**PRIMARY EXAMINER**